Docket No.: 2801-0165P
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Russell M. HAGAN et al.

Application No.: 09/985,679 | Confirmation No.: 4024

Filed: November 5, 2001 | Art Unit: 1617

For: NOVEL MEDICAL USE FOR TACHYKININ ANTAGONISTS | Examiner: S. Wang

INFORMATION DISCLOSURE STATEMENT
(SUBMISSION AFTER FILING OF AN APPLICATION BUT BEFORE FINAL REJECTION OR NOTICE OF ALLOWANCE OR CONCURRENTLY WITH A RULE 1.114 RCE APPLICATION)

MS RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Pursuant to 37 C.F.R. §§ 1.97 and 1.98, applicant(s) hereby submit(s) an Information Disclosure Statement for consideration by the Examiner.

I. LIST OF PATENTS, PUBLICATIONS OR OTHER INFORMATION

The patents, publications, or other information submitted for consideration by the Office are listed on the PTO-SB08(s), attached hereto.

II. COPIES

☒ a. Copies of cited U.S. patents and patent application publications are not included. Copies of foreign patent documents and non-patent literature are included.

☐ b. Some or all of the documents listed on the PTO-SB08 are not enclosed because they were cited in the International Search Report and copies should already be in the PTO file. If copies are needed, please contact the undersigned.

☐ c. REFERENCES PREVIOUSLY CITED OR SUBMITTED - Pursuant to 37 C.F.R. §1.98(d), consideration of information listed on the PTO-SB08 form(s) is requested since any patents, publications, or other information which are listed on the PTO-SB08 form(s) but for which copies are not enclosed herewith, were previously cited by or submitted to the PTO in one of the following applications which has been relied upon for an earlier filing date under 35 U.S.C. § 120:

U.S. Appl. No(s) and U.S. Filing Date

09/985,679 filed November 5, 2001

III. CONCISE EXPLANATION OF THE RELEVANCE

(check at least one box)

☐ a. DOCUMENTS IN THE ENGLISH LANGUAGE - The patents, publications, or other information listed on the attached PTO SB08 are in the English language and therefore, do not require a statement of relevancy.

☒ b. DOCUMENTS NOT IN THE ENGLISH LANGUAGE - A concise explanation of the relevance of all patents, publications, or other information listed that is not in the English language is as follows: A Partial English translation is provided for Introduction to Pharmacology New Ed. 1981, Nanzandoh Co., Ltd., Tokyo JP p. 7;

☐ c. ENGLISH LANGUAGE SEARCH REPORT - An English language version of the search report or action that indicates the degree of relevance found by the foreign office is attached, thereby satisfying the requirement for a concise explanation. See MPEP 609(III)(A)(3).

☐ d. OTHER - The following additional information is provided for the Examiner's consideration.

IV. FEES (check one box)

☐ a. This Information Disclosure Statement is being filed concurrently with the filing of a new patent application; therefore, no fee is required.

☐ b. This Information Disclosure Statement is being filed concurrent with the filing of a continuation-in-part, continuation, or divisional patent application; therefore, no fee is required.

☐ c. This Information Disclosure Statement is being filed within three months of the filing date of a national application (37 C.F.R. § 1.97(b)(1)). No fee or statement is required. *(This section is not to be used with RCE's.)*

☐ d. This Information Disclosure Statement is being filed within three months of the date of entry of the national stage as set forth in § 1.491 in an international application (37 C.F.R. § 1.97(b)(2)). No fee or statement is required.

☒ e. This Information Disclosure Statement is being filed concurrently with the filing of a Request for Continued Examination under § 1.114 (37 C.F.R. § 1.97(b)(4)). No fee or statement is required.

☐ f. This Information Disclosure Statement is being filed before the mailing date of a first Action on the merits (37 C.F.R. § 1.97(b)(3)). No fee or statement is required. In the event that a first Office Action on the merits has been issued, please consider this IDS under 37 C.F.R. § 1.97(c) and see the statement under 37 C.F.R. § 1.97(e) below, or, if no statement has been made, charge our deposit account for the fee as required by 37 C.F.R. § 1.17(p).

☐ g. This Information Disclosure Statement is being filed before the mailing date of a Final Office Action under 37 C.F.R. § 1.113 (See 37 C.F.R. § 1.97(c)(1)) or before the mailing date of a Notice of Allowance under 37 C.F.R. § 1.311 (See 37 C.F.R. § 1.97(c)(2)).

☐ No statement; therefore, a fee as required by 37 C.F.R. § 1.17(p) is attached.

or

☐ See the statement below. No fee is required.

V. STATEMENT UNDER 37 C.F.R. § 1.97(e)

(check only one box)

The undersigned hereby states that:

☐ **a. Each item of information contained in the IDS was first cited in any communication from a foreign Patent Office in a counterpart foreign application not more than 30 days prior to the filing of this IDS; or**

☐ b. Each item of information contained in the IDS was first cited in any communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS; or

☐ c. No item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of IDS was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of the IDS.

☐ d. Some of the items of information were cited in a communication from a foreign Patent Office. As to this information, the undersigned states that each item of information contained in the IDS was first cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS. As to the remaining information, the undersigned hereby states that no item of this remaining information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application and, to the best of my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this statement.

VI. PAYMENT OF FEES (check one box)

☐ The required fee is listed on the attached Fee Transmittal.

☒ No fee is required.

If the Examiner has any questions concerning this IDS, he/she is requested to contact the undersigned. If it is determined that this IDS has been filed under the wrong rule, the PTO is requested to consider this IDS under the proper rule and charge the appropriate fee to Deposit Account No. 02-2448.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

Dated: August 25, 2006

Respectfully submitted,

By _____
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Attorney for Applicant

Attachment(s):

- ☒ PTO-SB08
- ☒ Documents
- ☐ Foreign Search Report
- ☐ Fee
- ☐ Other:

PTO/SB/08a/b (07-05)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449A/B/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 2

Complete if Known	
Application Number	09/985,679-Conf. #4024
Filing Date	November 5, 2001
First Named Inventor	Russell M. HAGAN
Art Unit	1617
Examiner Name	S. Wang
Attorney Docket Number	2801-0165P

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number: Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	AA*	US-5,719,147	02-17-1998	Dorn et al.	
	AB*	US-6,048,859	04-11-2000	Dorn et al.	
	AC*	US-6,096,742	08-01-2000	Crocker et al.	
	AD*	US-6,235,735	05-22-2001	Dorn et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document: Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. * CITE NO.: Those application(s) which are marked with an single asterisk (*) next to the Cite No. are not supplied (under 37 CFR 1.98(a)(2)(iii)) because that application was filed after June 30, 2003 or is available in the IFW. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	CA	Marked-up Copy of EP 0 533 280 B1 for European Opposition Proceeding	
	CB	Decision by the European Patent Office on Opposition Proceedings on EP 0533280 B1	
	CC	Minutes of the Oral Proceedings Before the Opposition Division dated April 2, 2004	
	CD	Ctr. for Drug Evaluation and Research, Food and Drug Admin., Electronic Orange Book (24th ed. Cum. Supp. 6 June 2004) at <http://www.fda.gov/cder/ob/>, query "**Alosetron**". Patent data last updated August 11, 2004.	
	CE	Physicians' Desk Reference, PDR® Eelctronic Library™, PDR Entry for EMEMD® (**Aprepitant**), printed from website on August 11, 2004.	
	CF	Ctr. for Drug Evaluation and Research, Food and Drug Admin., Electronic Orange Book (24th ed. Cum. Supp. 6 June 2004) at <http://www.fda.gov/cder/ob/>, query "**Aprepitant**". Patent data last updated August 5, 2004.	
	CG	Physicians' Desk Reference, PDR® Eelctronic Library™, PDR Entry for ANZEMET® (**Dolasetron**), printed from website on August 11, 2004.	
	CH	Ctr. for Drug Evaluation and Research, Food and Drug Admin., Electronic Orange Book (24th ed. Cum. Supp. 6 June 2004) at <http://www.fda.gov/cder/ob/>, query "**Dolasetron**". Patent data last updated August 11, 2004.	
	CI	Physicians' Desk Reference, PDR® Eelctronic Library™, PDR Entry for KYTRIL® (**Granisetron**), printed from website on August 11, 2004.	
	CJ	Ctr. for Drug Evaluation and Research, Food and Drug Admin., Electronic Orange Book (24th ed. Cum. Supp. 6 June 2004) at <http://www.fda.gov/cder/ob/>, query "**Granisetron**". Patent data last updated August 11, 2004.	
	CK	Physicians' Desk Reference, Vol. 46, 1069-71 (1992), **Ondansetron** (brand name ZOFRAN®)	
	CL	Ctr. for Drug Evaluation and Research, Food and Drug Admin., Electronic Orange Book (24th ed. Cum. Supp. 6 June 2004) at <http://www.fda.gov/cder/ob/>, query "**Ondansetron**". Patent data last updated August 5, 2004.	

Examiner Signature		Date Considered	

PTO/SB/08a/b (07-05)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

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Filing Date	November 5, 2001
First Named Inventor	Russell M. HAGAN
Art Unit	1617
Examiner Name	S. Wang
Attorney Docket Number	2801-0165P

	CM	Physicians' Desk Reference, PDR® Eelctronic Library™, PDR Entry for ALOXI® (**Palonosetron**), printed from website on August 11, 2004.	
	CN	Ctr. for Drug Evaluation and Research, Food and Drug Admin., Electronic Orange Book (24th ed. Cum. Supp. 6 June 2004) at <http://www.fda.gov/cder/ob/>, query "**Palonosetron**". Patent data last updated August 11, 2004.	
	CO	Office Action issued by the European Patent Office on October 27, 2003, in coresponding European Application No. 99 200 338.4 - 2107	
	CP	Office Action issued by the European Patent Office on October 27, 2003, in coresponding European Application No. 99 200 337.6 - 2107	
	CQ	Introduction to Pharamcology, New Edition, 1981, Nanzandoh Co., Ltd.:Tokyo, Japan, p. 7	
	CR	Merck Index, 11th ed. (1989) p. 6802, Ondansetron	
	CS	Seyfried C.A. et al., Drug Metabolism and Drug Interactions, Vol. 9, No. 2, pp. 149-160, 1991	
	CT	L. Grélot et al., British Journal of Pharmacology (1998) 124, 1643-1650	
	CU	Watson et al., British Journal of Pharmacology 115, 84-94 (1995)	
	CV	Gonsalves et al., European Journal of Pharmocology 305, 181-185 (1996)	
	CW	Gardner et al., Regulatory Peptides 65, 45-53 (1996)	
	CX	Singh et al., European Journal of Pharmacology 321, 209-216 (1997)	
	CY	Rupniak et al., European Journal of Pharmacology 326, 201-209 (1997)	
	CZ	Gardner et al., Neuropharmacology 37, 1643-1644 (1998)	
	CA1	Tattersall et al., Neuropharmacology 39, 652-663 (2000)	
	CB1	Tsuchiya et al., Pharmacology 66, 144-152 (2002)	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1]Applicant's unique citation designation number (optional). [2]Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature		Date Considered	